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**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF NEW JERSEY**
**TRENTON DIVISION**

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| IN RE LIPITOR ANTITRUST LITIGATION | MDL Docket No. 2332<br>Master Docket No. 3:12-cv-2389<br>(PGS/DEA) |
| MEIJER, INC. and MEIJER DISTRIBUTION INC.,<br><br>Plaintiffs,<br><br>v.<br><br>PFIZER INC., PFIZER IRELAND PHARMACEUTICALS, WARNER-LAMBERT COMPANY, WARNER-LAMBERT COMPANY LLC, RANBAXY INC., RANBAXY PHARMACEUTICALS, INC. and RANBAXY LABORATORIES, INC.,<br><br>Defendants. | Civil Action No. 3:12-cv-4537<br>(PGS/DEA)<br><br>JURY TRIAL DEMANDED |

**AMENDED COMPLAINT AND DEMAND FOR JURY TRIAL**

Plaintiffs Meijer, Inc. and Meijer Distribution, Inc., (collectively "Plaintiffs") bring this civil action against Defendants Pfizer Inc., Pfizer Ireland Pharmaceuticals, Warner-Lambert Company, Warner-Lambert Company LLC, Ranbaxy, Inc, Ranbaxy Pharmaceuticals, Inc. and Ranbaxy Laboratories Limited under the antitrust laws of the United States. For their Complaint, Plaintiffs allege as follows:

## STATEMENT PRESERVING DISMISSED CLAIMS

1. Plaintiffs hereby preserve for purposes of appellate review those allegations and claims dismissed by this Court in its Memorandum and Order dated September 5, 2013, including but not limited to paragraphs 1-2, 44-152 and 163-211 of their initial Complaint and each Claim for Relief asserted in the Complaint to the extent that it incorporates and arises from those allegations.

## I. INTRODUCTION

2. This is a civil antitrust action challenging an unlawful and anticompetitive scheme by Defendants to maintain monopoly power and delay the entry of generic versions of the blockbuster brand-name drug Lipitor. Although the original compound patent for Lipitor expired March 24, 2010 and a follow-on patent expired June 28, 2011, generic entry did not occur until November 30, 2011. The Pfizer Defendants[1] and Ranbaxy[2] illegally caused this delay by implementing an anticompetitive scheme, which included entering into an unlawful market allocation agreement, pursuant to which Ranbaxy agreed not to launch a generic version of Lipitor in the United States until November 30, 2011 in exchange for various financial inducements from

[1] The "Pfizer Defendants" are Pfizer Inc., Pfizer Ireland Pharmaceuticals, Warner-Lambert Company, and Warner-Lambert Company LLC.

[2] "Ranbaxy" refers to Ranbaxy Inc., Ranbaxy Pharmaceuticals Inc., and Ranbaxy Laboratories Limited.

the Pfizer Defendants (the "Agreement"). Pursuant to and in furtherance of the Agreement, Defendants also thwarted other generic companies' efforts to obtain judicial declarations that the Pfizer Defendants' various unasserted patents were invalid, unenforceable and/or would not be infringed by generic Lipitor, in order to avoid the triggering of Ranbaxy's anticipated 180-day first-to-file marketing exclusivity and thereby sustain the Pfizer Defendants' and Ranbaxy's ability to, in concert, block other generic companies from launching generic Lipitor earlier than November 30, 2011.

3. The scheme worked as planned. Generic Lipitor was not sold until on or about November 30, 2011, later than it would have been sold absent Defendants' illegal, anticompetitive conduct.

4. Because of Defendants' scheme to delay generic Lipitor competition, in whole or in part, Plaintiffs have paid hundreds of millions of dollars more for atorvastatin calcium than they would have paid absent such conduct.

## II. JURISDICTION AND VENUE

5. This action arises under sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2, and section 4 of the Clayton Act, 15 U.S.C. § 15(a), to recover threefold damages, costs of suit and reasonable attorneys' fees for the injuries sustained by Plaintiffs resulting from Defendants' unlawful foreclosure of the United States market for atorvastatin calcium. The Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1337(a).

6. Defendants transact business within this district and/or have an agent and/or can be found in this district. Venue is appropriate within this district under section 12 of the Clayton Act, 15 U.S.C. § 22, 28 U.S.C. §1391(b) and (c) and 28 U.S.C. §1407.

## III. PARTIES

7. Plaintiffs Meijer, Inc. and Meijer Distribution, Inc. (collectively, "Meijer" or "Plaintiffs") are corporations organized under the laws of the State of Michigan, with their principal place of business located at 2929 Walker Avenue, NW, Grand Rapids, Michigan 49544. Meijer is the assignee of the claims of the Frank W. Kerr Co., which, during the relevant period, purchased Lipitor directly from Defendant Pfizer, Inc. and suffered antitrust injury as a result of the anticompetitive conduct alleged herein. Frank W. Kerr Co. resold to Meijer at least some of the Lipitor that it purchased from Defendant Pfizer, Inc. during the relevant period.

8. Defendant Pfizer, Inc. is a corporation organized and existing under the laws of the State of Delaware with a place of business at 235 East 42nd Street, New York, New York 10017. At all relevant times, Defendant Pfizer, Inc. engaged in the conduct challenged in this case and attributed to the Pfizer Defendants, itself and/or through its various employees and/or other agents acting within the course and scope of their duties and/or with actual, apparent, or ostensible authority in connection therewith.

9. Defendant Pfizer Ireland Pharmaceuticals, formerly known as Warner Lambert Export, Ltd., is a partnership organized and existing under the laws of Ireland, with registered offices at Pottery Road, Dun Laoghaire, Co. Dublin, Ireland. Pfizer Ireland Pharmaceuticals, a wholly-owned indirect subsidiary of defendant Pfizer, Inc., is the exclusive licensee of the '995 Patent and other patents. At all relevant times, defendant Pfizer Ireland Pharmaceuticals engaged in the conduct challenged in this case and attributed to the Pfizer Defendants, itself and/or through its various employees and/or other agents acting within the course and scope of their duties and/or with actual, apparent, or ostensible authority in connection therewith.

10. Defendant Warner-Lambert Company is a corporation formerly organized under the laws of the State of Delaware with offices for service of process at 235 East 42nd Street, New York, New York 10017. In 1997, Warner-Lambert and Pfizer began co-promotion of Lipitor. On June 19, 2000, Pfizer completed its merger with Warner-Lambert whereby Pfizer purchased all outstanding shares of Warner-Lambert common stock. Each share of Warner-Lambert stock was converted into 2.75 shares of Pfizer common stock. The merger qualified as a tax-free reorganization and was accounted for as a pooling of interests. Warner-Lambert Company became a wholly-owned subsidiary of Pfizer Inc. At the end of 2002, Warner-Lambert Company became a Delaware limited liability company and changed its name to Warner-Lambert Company LLC.

11. Warner-Lambert Company and Warner-Lambert Company LLC are collectively referred to as "Warner-Lambert."

12. Together, the defendants identified in the preceding four paragraphs are referred to herein as the "Pfizer Defendants."

13. Defendant Ranbaxy, Inc. is a corporation organized and existing under the laws of the State of Delaware, and has a place of business located at 600 College Road East, Princeton, New Jersey, 08540.

14. Defendant Ranbaxy Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, and has a place of business located at 600 College Road East, Princeton, New Jersey, 08540.

15. Defendant Ranbaxy Laboratories Limited is a corporation organized and existing under the laws of India, with a principal place of business located at Plot 90, Sector 32, Gurgaon-122001 (Haryana), India. At all relevant times, Defendants Ranbaxy Inc. and Ranbaxy

Pharmaceuticals Inc. acted in their own right and as agents of Defendant Ranbaxy Laboratories Limited.

16. Together, the defendants identified in the preceding three paragraphs are referred to herein as "Defendant Ranbaxy" or simply "Ranbaxy."

17. All of Defendants' actions described in this complaint are part of, and in furtherance of, the illegal monopolization and restraint of trade alleged herein, and were authorized, ordered, and/or done by Defendants' various officers, agents, employees, or other representatives while actively engaged in the management of Defendants' affairs, within the course and scope of their duties and employment, and/or with the actual, apparent, and/or ostensible authority of Defendants.

## IV. LEGAL BACKGROUND

### A. The Regulatory Structure for Approval of Generic Drugs and Substitution of Generics for Brand Name Drugs

18. Under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-392 ("FDCA"), a manufacturer of a new drug must obtain FDA approval to sell that new drug. The manufacturer must file a New Drug Application ("NDA") that includes data showing the drug is safe and effective as well as information about applicable patents.

19. After approval of an NDA, the brand manufacturer may list any patents that it believes could reasonably be asserted against a generic manufacturer who makes, uses, or sells a generic version of the brand name drug prior to the expiration of the listed patents in an FDA publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"). The FDA relies on the brand name manufacturer for information concerning the validity and applicability of the patents to the brand name drug. The FDA performs only a ministerial function in listing patents in the Orange Book.

20. Patents issued after the FDA approves an NDA may be listed in the Orange Book as related to the NDA if the manufacturer certifies, *inter alia*, that the new patents claim either the approved drug (for compound patents), or approved methods of use (for method-of-use patents). The NDA holder is required to list any new patents within 30 days of issuance. 21 U.S.C. §§ 355 (b)(1) & (c)(2).

21. Generic manufacturers may file abbreviated applications, or ANDAs, that (i) rely on the scientific findings of safety and effectiveness included in the brand name drug manufacturer's original NDA, and (ii) show that the generic drug contains the same active ingredient(s), dosage form, route of administration, and strength as the brand name drug (or, in other words, is Bioequivalent to the brand name drug). Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) ("Hatch-Waxman").

22. To obtain FDA approval of an ANDA, a generic manufacturer must certify that the generic drug will not infringe any patents listed in the Orange Book. An ANDA must contain one of four certifications. A Paragraph IV certification states "that the patent for the brand name drug is invalid or will not be infringed by the generic manufacturer's proposed product."

23. If a generic manufacturer files a Paragraph IV certification, the brand name manufacturer may delay the final FDA approval of the ANDA by suing for patent infringement. If the brand name manufacturer initiates a patent infringement action against the generic filer within 45 days of receiving notification of the Paragraph IV certification, the FDA may not grant final approval to the ANDA until the earlier of (a) the passage of 30 months, or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. The FDA may grant "tentative approval" while the 30-month stay is pending, but cannot authorize the generic manufacturer to go to market.

24. As an incentive to spur generic companies to provide alternatives to branded drugs, the first generic manufacturer to file a substantially complete ANDA containing a Paragraph IV certification gets a period of protection from competition with other ANDA filers for that drug. For Paragraph IV certifications made before December 2003, the first generic applicant is entitled to 180 days of market exclusivity, measured from its initial commercial marketing of the drug or court decisions determining that the patents for the branded drug listed in the FDA Orange Book are invalid or not infringed, whichever comes first.

25. The statutory rules in effect for ANDAs filed (and Paragraph IV certifications submitted) before December of 2003 create an opportunity for branded drug companies and first-filed ANDA applicants to collude to delay generic drug competition. A first-filed ANDA applicant can, in concert with the branded drug company, effectively "park" its 180-day exclusivity, and thereby create a "bottleneck" that prevents other ANDA applicants from coming to market indefinitely. The FTC has observed this potential and the anticompetitive effects that can result. Federal Trade Commission, Generic Drug Entry Prior to Patent Expiration, An FTC Study, at vi-xi (FTC July 2002).

26. It is generally not in a first-filed ANDA applicant's unilateral economic interest to park its 180-day exclusivity.

27. Brand name manufacturers have large financial incentives to: (a) list patents in the Orange Book, even if such patents are not eligible for listing; and (b) sue any generic competitor that files an ANDA with a Paragraph IV certification, even if the competitor's product does not actually infringe the listed patent(s) and/or the patents are invalid or unenforceable, in order to delay final FDA approval of an ANDA for up to 30 months.

**B. The Benefits of Generic Drugs**

28. Once a generic manufacturer establishes that its generic drug is bioequivalent to a corresponding branded drug, the FDA assigns an "AB" rating to the generic drug, permitting it to be sold and also substituted for the brand name drug at the pharmacy counter. Typically, AB-rated generics are priced significantly below their branded counterparts. Upon the entry of additional generics, drug prices generally fall even further.

29. Generic competition enables purchasers to (a) purchase generic versions of the brand name drug at a substantially lower price than the brand name price, and (b) purchase the brand name drug at a reduced net price. Generic competition can result in billions of dollars in savings to consumers, insurers, and other drug purchasers.

30. All states permit (and some states require) pharmacists to automatically substitute a generic drug for the corresponding brand name drug unless the doctor has stated that the prescription for the brand name product must be dispensed as written. Until a generic manufacturer enters the market, no such substitution can occur and therefore the brand name manufacturer can charge supracompetitive prices profitably without material loss of sales volume. Consequently, brand name drug manufacturers have a strong interest in seeking to delay the introduction of generic competition into the market.

31. Many third party payors (such as health insurance plans and Medicaid programs) have adopted policies to encourage the substitution of AB-rated generic drugs for their branded counterparts. Many consumers routinely switch from a branded drug to an AB-rated generic drug once the generic becomes available. Consequently, AB-rated generic drugs typically capture a significant share of their branded counterpart's sales, causing a significant reduction of the branded drug's unit and dollar sales.

## V. FACTS

### A. Statins

32. Lipitor belongs to a class of drugs called statins. Discovered in the 1970s, statins lower cholesterol by inhibiting the liver enzyme 3-hydroxy 3-methylglutrayl-coenzyme A reductase ("HMG-CoA reductase"). HMG-CoA reductase controls the rate of the metabolic production of cholesterol; inhibiting HMG-CoA reductase inhibits the production of cholesterol.

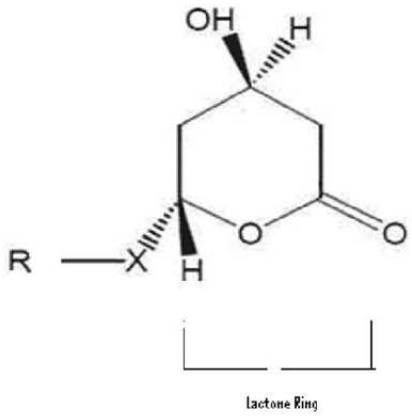
33. Common thinking is that high cholesterol is associated with coronary heart disease and atherosclerosis in some populations.

34. Efforts to reduce cholesterol levels are a big business: by 1997, five of the largest pharmaceutical companies marketed and sold six different brand name statins. In 2002, almost one in ten Americans aged 20 and older took a statin. In 2004, sales of statins topped $15.5 billion, comprising 6.6% of all prescription drug sales.

35. Branded statins cost between $2.50 and $5.00 a day ($75 to $150 a month, $900-$1,800 a year); generic statins cost markedly less, sometimes less than $1 a day.

36. Statins consist of three structural parts: a lactone ring, a linkage group (denoted as "X"), and a group or groups connected to the linkage group (referred to herein as an "R group").

**Figure 1: Generalized Structure of Statins[3]**




37. The R group for the well-known statins can contain one or more single rings or fused rings, and other substituent groups.

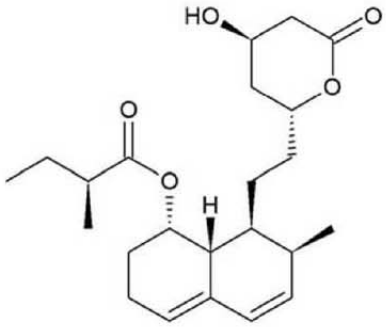
38. The lactone ring, on the right hand side, contains five carbons and one oxygen.[4] Attached to the ring and denoted as =O is an additional oxygen called a *ketone.* The lactone ring has two major substituents: a hydroxyl group (-OH) shown at the top of the ring, and the linkage group, X, attached to the R group. The two major substituents in the lactone ring are in a *trans* position; that is, the hydroxyl group is above the plane of the lactone ring and the linkage group X is below the plane of the lactone ring.

[3] The three-dimensional structure of molecules can be represented pictorially in two dimensions using the following symbols to represent the orientation of the atoms in space: ◥ (solid wedge) indicates that the molecule is projecting out of the page; ⁞ (dashed wedge) indicates that the molecule is projecting behind the page; — (solid line) indicates that the molecule is in the plane of the paper.

[4] The lactone ring members are shown with the chemical convention that omits the carbon and some hydrogen atoms and shows only the bonds between the carbons and other atoms. Each carbon atom is designated as the point where two bond lines connect and each carbon is assumed to have to hydrogen atoms attached.

39. In the 1970s, researchers discovered that mevastatin, naturally occurring in red yeast and rice, inhibited cholesterol synthesis.

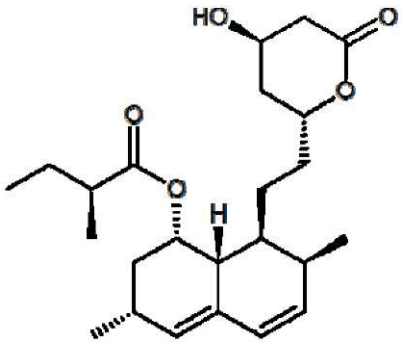
**Figure 2: Mevastatin**




40. Mevastatin contains the lactone ring as shown in Figure 1 (top right of Figure 2), a linkage group, X (shown as  ), and an R group of two fused rings with substituents. One of the fused rings contains a methyl group (-$CH_3$, shown as  ) on the right ring and an additional O-linked substituent group on the left ring.

41. Around the same time, researchers discovered that lovastatin, naturally occurring in red yeast rice and oyster mushrooms, was another highly potent HMG-CoA reductase inhibitor. Merck sought and gained approval for Mevacor, a brand name version of lovastatin and the first statin available in the United States, in the early 1980s.

**Figure 3: Lovastatin**




42. The structure of lovastatin is similar to mevastatin. Lovastatin contains a lactone ring and a fused-ringed group joined to the lactone ring by a linkage group. The R group contains the same fused rings with same O-linked substituent group on the left ring and a methyl group on the right ring as found on mevastatin. Lovastatin has an additional methyl group.

43. In the early 1980s, Warner-Lambert sought to enter the market by developing a "me-too" version of the already-identified statins. Researchers at Warner-Lambert came up with a formulation that used the same lactone ring as mevastatin and lovastatin but contained different linked substituents. Warner-Lambert called their new statin "atorvastatin."

**B. Warner-Lambert Obtained the Original Lipitor Patent**

44. On May 30, 1986, Warner-Lambert filed a patent application for a group of compounds and pharmaceutical compositions useful as hypercholesterolemic and hypolipidemic agents.[5] The patent application was entitled "*Trans-6-[2-(3- or 4-Carboxamido-Subsituted Pyrrol-1-yl)alkyl]-4-Hydroproxypyran-2-one Inhibitors Of Cholesterol Synthesis.*"

[5] The application was in the name of Bruce D. Roth. Dr. Roth was, at all relevant times, a leader of the drug discovery team at Warner-Lambert that developed Lipitor. He is the named inventor of Patent Nos. 4,681,893 and 5,273,995; the patent applicant for Patent Nos. 4,681,893 and 5,273,995; and the patent applicant in connection with the re-issuance proceedings for Patent No. 5,273,995.

45. This application would eventually lead to the issuance of the '893 Patent, which the PTO issued on July 21, 1987.[6] The '893 Patent was assigned to Warner-Lambert. In the absence of an extension, the Original Lipitor Patent would have expired on May 30, 2006, twenty years from the date of the first application. Later extensions lengthened the period of patent protection until March 24, 2010.

46. The '893 Patent envisioned formulations containing only the R-trans or S-trans enantiomers of compounds of structural formula I. The '893 Patent also recognized that these compounds could be in acid or salt form. While the '893 Patent covered multiple formulations of atorvastatin, Warner-Lambert focused on developing and commercializing the R-trans enantiomer of atorvastain in calcium salt form. The '893 Patent thus covered atorvastatin.

47. Although the '893 Patent was expected to provide Warner-Lambert with many years of patent protection and many years of exclusive sales of Lipitor, Warner-Lambert nevertheless sought to extend *even further* the period for exclusive sales for its new statin.

**C. Warner-Lambert Obtained the Follow On Enantiomer Patent**

48. In 1989, in an effort to obtain even longer patent exclusivity for Lipitor, Warner Chilcott applied for a patent that specifically claimed the isolated R-trans enantiomer of atorvastatin in various forms, including the calcium salt used as the active ingredient in Lipitor. This patent ultimately issued as U.S. Patent No. 5,273,995 ("the '995 Patent").

49. In seeking this patent, Warner-Lambert faced certain realities. Warner-Lambert knew that the R-trans enantiomer was the active enantiomer responsible for atorvastatin's ability to inhibit cholesterol. Warner-Lambert also knew that the PTO would reject an application to patent

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Patent Nos. 4,681,893 and 5,273,995 issued to Dr. Roth and were assigned to his employer, Warner-Lambert.

an enantiomer covered by the '893 Patent; after all, such an "invention" would be either anticipated (that is, already covered) by the '893 Patent, or obvious in light of the '893 Patent. Thus, Warner-Lambert knew it could obtain a follow-on patent specifically for the R-trans enantiomer only if it could convince the PTO that the isolated R-trans enantiomer had a surprising or unexpected characteristic.

50. Senior management at Warner-Lambert instructed the Warner-Lambert researchers to review the **pre-existing** biological data for the R-trans enantiomer to find data that supported both (i) a claim that the activity of the isolated R-trans enantiomer was surprising and (ii) the patentability of the isolated R-trans enantiomer. Regarding the instructions from these senior Warner-Lambert officials, Dr. Roth, the inventor, testified:

> [I]f I found something surprising I would provide that. And what I did do was I provided that information to the patent attorney for Warner-Lambert and asked if that was sufficient, and it was and so that was the data that was used.

51. In the application, Warner-Lambert relied on the results of that search, asserting: "It is now **unexpectedly found** that the enantiomer having the R form of [a] ring-opened acid [described in the '893 Patent] … **provides surprising inhibition** of the biosynthesis of cholesterol." Warner-Lambert further asserted that "an ordinarily skilled artisan may not predict the **unexpected and surprising inhibition** of cholesterol biosynthesis of the present invention in view of [prior] disclosures." In support of this contention, Warner-Lambert presented only one piece of evidence: a short table stating that Warner-Lambert's Cholesterol Synthesis Inhibition ("CSI") assay data demonstrates the R-trans enantiomer is **one hundred-times more active** than

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[6] The PTO conducted two separate reexamination proceedings with respect to the '893 Patent. Neither of these reissue proceedings is relevant to Plaintiffs' claims in this matter.

the S-trans enantiomer, and **ten-times more active** than the racemate, in inhibiting the synthesis of cholesterol *in vitro* ("CSI Table"):

is now also incorporated by reference therefor. The CSI data of the compound I, its enantiomer the compound II and the racemate of these two compounds are as follows:

| Compound | $IC_{50}$ (micromoles/liter) |
|---|---|
| [R-(R*R*)] isomer | 0.0044 |
| [S-(R*R*)] isomer | 0.44 |
| Racemate | 0.045 |

Accordingly, the present invention is the pharmaceutical composition prepared from the compound of the formula I or II or pharmaceutically acceptable salts thereof.

52. Warner-Lambert claimed the "present invention" -- the R-trans enantiomer -- was ten times more powerful than its racemate in inhibiting cholesterol synthesis based on the data presented in the CSI table.

53. A "CSI assay" measures the ability of a compound to inhibit cholesterol biosynthesis along the entire cholesterol biosynthesis pathway and is one of the most commonly used methods to test a compound's ability to inhibit the synthesis of cholesterol *in vitro.* The CSI test does not identify the specific step in the cholesterol biosynthetic pathway that is being inhibited, nor is it specific to HMG-CoA reductase. The results of a CSI assay are reported as an $IC_{50}$ value, the concentration of a test compound that produces 50% inhibition in the conversion of cholesterol-[$^{14}$C] acetate to radioactive cholesterol.[7]

54. One skilled in the art of statins in 1989 would have expected the active R-trans enantiomer to be about twice as active as the racemate in inhibiting cholesterol synthesis. Activity

[7] Two other commonly used methods of measuring a compound's inhibition of cholesterol are the *in vivo* Acute Inhibition of Cholesterol Synthesis ("AICS") assay and the *in vitro* CoA Reductase Inhibition ("COR") assay. The COR assay measures a compound's ability to inhibit HMG-CoA reductase specifically and is typically used to confirm that the activity seen in the CSI assay is attributable to inhibition of the desired target: HMG-CoA reductase.

of one enantiomer that is more than ten times that of the racemate would have been "unexpected" and "surprising" if the findings were based on true or accurate data. In truth, they were not.

55. The CSI Table purported to present reliable scientific data. It did not. In truth, it contained limited data cherry-picked from multiple flawed tests conducted over several years using different formulations of various atorvastatin salts. And the biological data was false: reliable data actually shows that the R-trans enantiomer is, as expected, only about two times more active than the racemic mixture -- not the ten-fold increase Warner-Lambert claimed.

56. Acknowledging that the isolated R-trans enantiomer is *prima facie* obvious over the '893 Patent, Warner-Lambert argued to the patent examiner that the obviousness is overcome by the "surprising" and "unexpected" ten-fold increase in activity claimed a declaration by Dr. Roth ("Roth Declaration").

57. The PTO relied on the Roth Declaration and the CSI Table to find that the R-trans enantiomer was not obvious in light of the '893 Patent. The Board of Appeals explicitly (i) directed the examiner to re-evaluate the application for obviousness, and (ii) stated that an obviousness rejection appeared to be appropriate. The examiner did precisely that. The examiner relied on Warner-Lambert's claim of "surprising" and "unexpected" activity and determined that the charts presented in support of that claim (both in the patent specification itself and the Roth Declaration) were sufficient to overcome a rejection on obviousness grounds. The only "surprising" or "unexpected" characteristic of the isolated R-trans enantiomer Warner-Lambert claimed was the ten-fold increase in activity compared to the racemic mixture. The only data presented in support of those claims were contained in the patent specification (the CSI Table) and Roth Declaration.

58. On March 16, 1993, apparently without any further formal proceedings or briefing, the PTO issued a Notice of Allowability for the follow-on, isolated R-trans enantiomer patent application. The '995 Patent issued on December 28, 1993 and expired on June 28, 2011.

### D. The FDA Approved Lipitor, and the Original Lipitor Patent Provided Years of Patent Protection

59. On June 17, 1996, Warner-Lambert submitted a new drug application under § 505(b) of the FDCA and 21 C.F.R. § 314.50, seeking approval to sell atorvastatin calcium. The formulation developed for FDA approval and commercialization was atorvastatin calcium, *i.e.*, the isolated R-trans enantiomer formulated as a calcium salt. On December 17, 1996, the FDA approved atorvastatin calcium -- brand named "Lipitor" -- for the treatment of hypercholesterolemia and mixed dyslipidemia. The FDA initially approved 10 mg, 20, mg, and 40 mg tablets, adding approval of 80 mg tablets on April 7, 2000.

#### 1. The Orange Book Listings for Lipitor

60. Following approval, under 21 U.S.C. § 355, Warner-Lambert listed both the '893 Patent and the '995 Patent in the FDA Orange Book. By listing both patents in the Orange Book, the Pfizer Defendants forced any generic company seeking approval of an ANDA for generic atorvastatin calcium to file a Paragraph IV certification as to both the '893 and '995 Patents if the generic company wished to enter the market prior to the expiration of both patents. Such a certification would, the Pfizer Defendants knew and intended, trigger the ability of Warner-Lambert to file infringement litigation, which in turn would trigger the statutory Hatch-Waxman 30-month stay of ANDA approval.

61. At the time of FDA approval of Lipitor, the '893 Patent was scheduled to expire on May 30, 2006. The '995 Patent, by contrast, was scheduled to expire on December 28, 2010.

62. The Pfizer Defendants also listed the following patents in the FDA Orange Book as covering Lipitor: 6,126,971 (the "'971 Patent"); 5,686,104 (the "'104 Patent"); and 5,969,156 (the "'156 Patent"). Both the '104 and '971 patents cover particular, and narrow, ways of formulating atorvastatin calcium with various excipients to stabilize the finished pharmaceutical product. These two patents are referred to as the "Unasserted Formulation Patents"; "unasserted" because, despite later efforts by generic companies to enter the market, Pfizer did not assert these two patents against those generic companies (including Ranbaxy). The '156 patent covered the crystalline form of atorvastatin calcium, not the amorphous form. Ranbaxy's product used the amorphous form.

63. As a practical matter, Pfizer knew that potential generic competitors could (and did) design-around these narrow process or formulation patents. No reasonable litigant would have had any expectation of succeeding against Ranbaxy on a claim alleging infringement of the '971, '104 or '156 patents. Such an infringement claim would have been an objectively baseless sham.

**2. The '893 Original Lipitor Patent Protected the Lipitor Franchise for Years**

64. Shortly after FDA approval, Warner-Lambert filed with the PTO an application under 35 U.S.C. § 156 for an extension of the term of the '893 Patent. Section 156 provides that the period of patent protection may be extended in order to account for the time lag between the issuance of a patent covering the active ingredient in a new drug, and FDA approval. The time between patent issuance and FDA approval can be significant, and this statute allows the PTO to extend the term of pharmaceutical patents to make up for this lost time on the market.

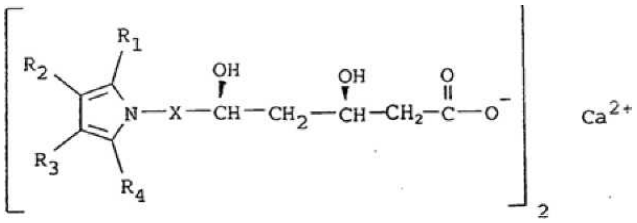
65. Warner-Lambert asked the PTO to extend the period of market exclusivity granted by the '893 Patent -- not the '995 Patent -- for about three years and four months. Again,

Warner-Lambert took the position that the '893 Patent covered the isolated R-trans enantiomer, atorvastatin calcium.

66. Warner-Lambert informed the PTO that (i) the FDA had approved Lipitor, (ii) the active ingredient in Lipitor was atorvastatin calcium, and (iii) atorvastatin calcium was claimed by the '893 Patent. Warner-Lambert represented that the '893 Patent claimed atorvastatin calcium as a new chemical entity (Claims 1-4), as a pharmaceutical composition (Claim 8), and as a method to inhibit cholesterol biosynthesis (Claim 9).

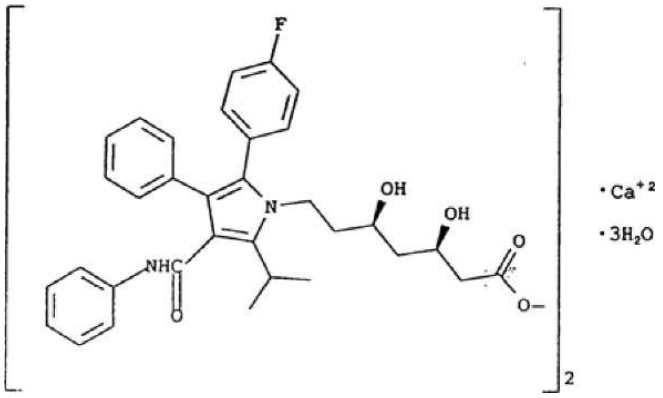
67. Claim 1 requires "a compound of structural formula I" or "a hydroxyl acid or pharmaceutically acceptable salt thereof, corresponding to the opened lactone ring of the compounds of structural formula I above." In the extension application, Warner-Lambert claimed that Lipitor is a pharmaceutically acceptable salt of structural formula I, and thus covered by Claim 1 of the '893 Patent:

> Lipitor is a pharmaceutically acceptable salt (i.e., calcium salt) of the hydroxy acid corresponding to the opened lactone ring of a compound of structural formula I. Lipitor has the general structure:



where; **X** is **-CH$_3$CH$_2$-**
**Ri** is 4-**f**luorophenyl;
**R$_2$** is phenyl;
**R$_3$** is **-CONH-**phenyl; and
**Rj** is **1**-methylethyl, an alkyl group having three carbon atoms.

Lipitor™ thus has the specific chemical structure



68. The PTO granted the patent term extension on July 15, 1998. With both an extension for the time spent pursuing FDA approval of Lipitor under Section 156, and then for pediatric testing pursuant to the statutory provisions of the FDCA providing for additional marketing exclusivity, the '893 Patent ultimately expired on March 24, 2010.

69. The Pfizer Defendants also sought and obtained a six-month extension for pediatric testing for the '995 Patent pu rsuant to the FDCA on February 22, 2002. As a result, the expiration date of the '995 Patent was June 28, 2011.

70. The '893 Patent ultimately provided more than thirteen years of patent exclusivity to market and sell branded Lipitor -- from the 1997 launch until March of 2010. The '995 Patent

tacked on, if enforced by Warner-Lambert or its successors, additional freedom from generic Lipitor competition.

### 3. In 1997, Warner-Lambert and Pfizer Launched Lipitor

71. Prior to commercialization, Warner-Lambert decided to employ a "saturation" approach to selling Lipitor. The intent of the "saturation" strategy was to have as many sales representatives as possible contacting physicians. As Anthony Wild, Warner-Lambert Pharmaceutical Sector President, explained, "[t]he more soldiers you have out there, the more guns, the more likely you are to achieve your ends." Warner-Lambert clearly understood that the sales force was a key success factor in any drug's performance, but a 1995 sales force deployment study revealed that the Warner-Lambert's sales force was inadequate in size and focus to effectively launch Lipitor.

72. Warner-Lambert chose Pfizer to assist in marketing Lipitor. Warner-Lambert and Pfizer outgunned the competition with the largest sales force ever. Between Warner-Lambert and Pfizer, more than 2,200 sales representatives were believed to be selling Lipitor during its launch in the U.S.

73. Lipitor reached $1 billion in domestic sales within 12 months of its January 1997 launch. By the end of 1998, Lipitor was available for sale in 50 countries. In October 1997, 30% of all new statin prescriptions were written for Lipitor.

## E. The Pfizer Defendants' Litigation Against Ranbaxy Based on the '995 Patent

74. Ranbaxy was the first to file an ANDA for generic Lipitor. On August 19, 2002, Ranbaxy filed ANDA 76-477, seeking approval to sell a generic version of Lipitor in the 10, 20, 40, and 80 mg tablet strengths.

75. As the first to file a substantially-complete ANDA for generic atorvastatin calcium, Ranbaxy was entitled to 180 days of marketing exclusivity under the then-effective provisions of the FDCA. No other ANDA applicant for generic Lipitor could receive FDA approval until the expiration of Ranbaxy's period of marketing exclusivity, which would not commence running until the earlier of either the inception of Ranbaxy's actual commercial marketing or one or more court decisions obtained by Ranbaxy or another ANDA filer that the patents listed in the FDA's "Orange Book" as claiming Lipitor were invalid or not infringed.

76. In or around February of 2003, Ranbaxy sent two Paragraph IV certifications to the Pfizer Defendants with respect to all patents listed in the Orange Book, including the '995 Patent. In them, Ranbaxy asserted that no valid patent claims covering Lipitor would be infringed by the sale, marketing, or use of Ranbaxy's ANDA product.

77. In response, the Pfizer Defendants, within the 45-day period provided by the Hatch-Waxman statutory scheme, filed an action in the United States District Court for the District of Delaware, alleging that Ranbaxy's ANDA product would infringe the '893 and '995 Patents.

78. From 2003 to 2006, the Pfizer Defendants' infringement litigation against Ranbaxy based upon the '893 and '995 Patents progressed through discovery, a trial, and an eventual appeal and decision by the United States Court of Appeals for the Federal Circuit. At the time the district court rendered its decision regarding the '995 Patent in December of 2005, neither the district court nor Ranbaxy had the benefit of all of the evidence regarding the prosecution of the '995 Patent.

79. On November 2, 2006, the Court of Appeals reversed the lower court's decision regarding the '995 Patent, determining that claim 6, the sole claim that the Pfizer Defendants claimed Ranbaxy's ANDA product infringed, was technically invalid. The Federal Circuit did not address the district court's determination that the '995 Patent was not invalid for obviousness, nor

did it address any of the other claims in the Patent. The Federal Circuit affirmed the ruling that the '893 patent was valid and would be infringed by Ranbaxy's product.

80. Based upon the Court of Appeals' mandate, the district court, on November 7 and 30, 2006, amended its Final Judgment Order to enjoin the effective date of any approval of Ranbaxy's ANDA for generic Lipitor until March 24, 2010, the expiry of the '893 Patent, and to remove from its Final Judgment Order any prohibition of effective FDA approval of Ranbaxy's ANDA based on the '995 Patent. On information and belief, the district court's Final Judgment Order, as amended, was sent by the Pfizer Defendants and Ranbaxy to the FDA.

### F. The Pfizer Defendants and Ranbaxy Entered Into the Illegal Horizontal Market Allocation Agreement

81. The Pfizer Defendants and Ranbaxy knew and/or believed that Ranbaxy was the first filer of an ANDA for generic Lipitor. As a result, the Pfizer Defendants and Ranbaxy both knew and/or believed that Ranbaxy would enjoy the ability to market its generic Lipitor for 180 days free from competition from other ANDA filers.

82. The Pfizer Defendants and Ranbaxy also knew that Ranbaxy's 180-day exclusivity would give Ranbaxy the ability -- simply by refraining from launching its own generic Lipitor or from relinquishing the right to its 180-day exclusivity period -- to prevent other generic competitors from entering the United States market.

83. Consequently, all the Pfizer Defendants needed to do to delay all generic Lipitor competition was enter into an agreement with Ranbaxy under which Ranbaxy would agree to delay the launch of its generic version of Lipitor. As Defendants knew, such an agreement would create a nearly-insurmountable obstacle to generic competition for all ANDA filers for the duration of any such agreement.

84. That is just what the Pfizer Defendants and Ranbaxy did. On June 17, 2008, after the only claim of the '995 Patent upon which the Pfizer Defendants had sued Ranbaxy had been declared invalid, the Pfizer Defendants and Ranbaxy, ostensibly to settle patent litigation, entered into an unlawful "reverse-payment" Agreement.

85. The Agreement constituted an unlawful contract, combination and conspiracy to allocate the entire United States market for atorvastatin calcium to the Pfizer Defendants until November 30, 2011.

86. Pursuant to the Agreement, Ranbaxy agreed that it would not compete "directly or indirectly" with the Pfizer Defendants by selling or authorizing the sale of generic Lipitor in the United States market until November 30, 2011, more than 20 months after the expiration of the '893 Patent. Absent the Agreement, Ranbaxy would have been highly motivated to seek to introduce generic Lipitor no later than June 28, 2011 , given the enormous profit opportunity generic Lipitor presented to Ranbaxy and other ANDA filers, and given the FDA's desire to permit ANDA filers to bring low-cost generic products to market as soon as possible.

87. In exchange for Ranbaxy's agreement not to launch generic Lipitor directly or indirectly until November 30, 2011, the Pfizer Defendants gave Ranbaxy substantial financial consideration, including the settlement and effective forgiveness of Pfizer's claims against Ranbaxy for damages in those parties' patent litigation over the Pfizer drug Accupril. As explained in more detail below, Ranbaxy paid $1 million to "settle" a claim by Pfizer that the record in the Accupril litigation shows was likely worth hundreds of millions of dollars. This settlement was not an arms-length settlement for fair value, but rather a means of compensating Ranbaxy to delay its launch of generic Lipitor. Ranbaxy's $1 million payment was less than what Ranbaxy likely would have spent just to defend the claim and, given the strength of Pfizer's claim, the

agreement makes no economic sense other than as a means of paying Ranbaxy for delaying its introduction of generic Lipitor.

88. In May 2004, Pfizer established the validity and enforceability of its patent covering Accupril in patent litigation with Teva Pharmaceuticals USA, Inc. ("Teva") before Judge Debevoise of the District of New Jersey. *See Warner-Lambert Co. v. Teva Pharms. USA, Inc.*, 2004 U.S. Dist. LEXIS 12915 (D.N.J. June 29, 2004). On appeal, the Federal Circuit affirmed the finding of enforceability and remanded for further proceedings on certain issues relating to validity and infringement. *See Warner-Lambert Co. v. Teva Pharms. USA, Inc.*, 418 F.3d 1326 (Fed. Cir. 2005). On remand, the district court granted Pfizer's motion for summary judgment of infringement. 2006 U.S. Dist. LEXIS 3539 (D.N.J. Jan. 31, 2006). The district court then held a bench trial on the sole remaining issue relating to validity and entered judgment in favor of Pfizer. 2007 U.S. Dist. LEXIS 87669 (D.N.J. Nov. 29, 2007).

89. Ranbaxy had an ANDA pending for its own generic version of Accupril but was blocked from obtaining final FDA approval due to Teva's 180-day exclusivity as the first filer. As a result, Ranbaxy and Teva entered into an agreement under which Teva agreed to relinquish its exclusivity in favor of Ranbaxy and Ranbaxy agreed to provide Teva with its FDA-approved product for sale in the United States. *See Pfizer, Inc. v. Teva Pharms. USA, Inc.*, 429 F.3d 1364, 1371 (Fed. Cir. 2005). Pursuant to this agreement, Ranbaxy received final FDA approval and Teva launched Ranbaxy's FDA-approved generic Accupril in December 2004.

90. Pfizer then sued Ranbaxy and Teva for patent infringement, and the case was assigned to Judge Debevoise. Pfizer sought treble damages for willful infringement. In that action, Pfizer moved for and obtained a preliminary injunction halting all generic sales of Ranbaxy's generic version of Accupril, but not before Ranbaxy's generic had "decimated" Pfizer's

sales. Pfizer's sales of Accupril in 2004 were approximately $525 million, while in 2005 (the year after Teva's and Ranbaxy's December 2004 generic launch), its sales were only $71 million. If found liable for infringement, Ranbaxy and Teva would have been responsible for the damages resulting from that loss of sales.

91. In obtaining a preliminary injunction, Pfizer had proven a strong likelihood that it would prevail on the merits of its infringement claims, a ruling that the Federal Circuit affirmed. *See Pfizer, Inc. v. Teva Pharms. USA, Inc.*, 2005 U.S. Dist. LEXIS 29050 (March 31, 2005), *aff'd*, 429 F.3d 1364 (Fed. Cir. 2005).

92. Pfizer posted a $200 million bond in connection with the injunction and informed the court that Ranbaxy's and Teva's sales of "massive quantities" of generic Accupril had "decimated" Pfizer's Accupril sales. Pfizer sought both lost profits and enhanced damages for willful infringement.

93. Teva, Ranbaxy's marketing partner and co-defendant, informed the court that it would not seek to relitigate the validity and enforceability rulings in the prior pre-marketing Hatch-Waxman case. Ranbaxy conceded that it "absolutely" infringed under the claim construction adopted by the court and affirmed on appeal. *See Pfizer, Inc. v. Teva Pharms. USA, Inc.*, 429 F.3d 1364, 1377 (Fed. Cir. 2005) ("Ranbaxy conceded in the preliminary injunction hearing that its formulation 'absolutely' literally infringes claim 16 if 'saccharides' is construed to include polysaccharides"). As a result of these prior rulings, it was overwhelmingly likely that Ranbaxy would have been found liable to Pfizer for substantial damages if the case had proceeded to judgment.

94. In exchange for Ranbaxy's agreement to delay the introduction of generic Lipitor, Pfizer agreed to dismiss its Accupril damages suit against Ranbaxy for a token payment of $1

million, which was far below the value of the claim. The huge difference between the amount that Ranbaxy paid in settlement and the amount that it was likely to owe if the Accupril case proceeded to judgment represented a payment to Ranbaxy of hundreds of millions of dollars to delay generic Lipitor.

95. In addition to agreeing to drastically reduce Ranbaxy's liability for selling infringing generic Accupril, Pfizer paid Ranbaxy by giving Ranbaxy the right to market generic Lipitor in eleven foreign markets outside the United States on dates specified in the settlement agreement, in most cases, September 6, 2011, or, if Pfizer obtained pediatric exclusivity in the relevant market, March 6, 2012. Ranbaxy agreed not to sell generic Lipitor in the foreign markets prior to the specified dates. These foreign rights provided no benefit of any kind to American drug purchasers. Therefore, even assuming that they provided a benefit of some kind to consumers in the foreign markets, these rights represented a nonmonetary means of compensating Ranbaxy for delaying its launch of generic Lipitor in the United States, not a counterweight to the harm suffered by purchasers in the United States. The federal antitrust laws are concerned with competitive conditions in the United States, not in Malaysia or Vietnam.

96. Absent these enormous financial inducements, Ranbaxy would not have agreed to delay its launch of generic Lipitor and would instead have launched no later than June 28, 2011, when the '995 Patent expired.

97. The Pfizer Defendants also purported to license their Lipitor patents to Ranbaxy, but that "consideration" was a sham, illusory, and merely included in the Agreement to disguise the illegal horizontal agreement to allocate the entire United States market for atorvastatin calcium.

98. In fact and at law, no reasonable litigant would have believed that any patent even colorably put Ranbaxy (or any other relevant ANDA filer) in danger of liability for infringement on sales made after June 28, 2011.

99. An infringement case against Ranbaxy (or any other ANDA filer), based upon any legitimately-obtained Lipitor patent that expired after June 28, 2011, was or would have been an objectively baseless sham. Neither the Pfizer Defendants nor Ranbaxy subjectively believed that Pfizer had intellectual property protection after June 28, 2011 or that there was any such threat of infringement liability from such patents.

100. The Pfizer Defendants were well aware of the lack of exclusionary power of its intellectual property after June of 2011, when the '995 Patent was set to expire. In 2005, before entering into the Agreement with Ranbaxy, Pfizer's former Chairman and CEO stated:

> There are dozens of generic drug manufacturing companies with a red circle around June 28, 2011. That's the day the patent for our anti-cholesterol medication Lipitor expires. . . . Shortly thereafter a number of generic alternatives to Lipitor will be introduced and consumers will have a choice of generic tablets containing atorvastatin calcium[.]

101. Of course, only the '995 Patent expired in June of 2011. Other Pfizer patents related to atorvastatin calcium -- namely the Unasserted Formulation Patents, the '156 Patent, and the Process Patents (more specifically described above and below) -- were to expire between 2013 and 2017. If the Unasserted Formulation Patents, the Process Patents, and/or the '156 Patent had any potential to legitimately keep generic Lipitor off the market, Pfizer's CEO would not have ignored them and the literally tens of billions of dollars they would have conferred on his company. His statement that June 28, 2011 is the key date only makes sense if one recognizes -- as the Pfizer Defendants did -- that the Unasserted Formulation Patents, the Process Patents, and the '156 Patent could not block generics from entering.

102. As of the date of the Agreement, the only means by which the Pfizer Defendants could have prevented a launch by Ranbaxy of generic Lipitor on or after June 28, 2011 was convincing the PTO to reissue the '995 patent and using it to obtain an injunction.

**1. The "Process Patents"**

103. As of the date of the Agreement, the only pending patent litigation by the Pfizer Defendants against Ranbaxy involving Lipitor was litigation alleging infringement of specific processes for making atorvastatin calcium, taught in U.S. Patent Nos. 6,274,740 (the "'740 Patent") and 6,087,511 (the "'511 Patent") (together the "Process Patents").

104. The Pfizer Defendants had no realistic likelihood of meeting their burden of establishing that Ranbaxy infringed these Process Patents. The Process Patents afforded the Pfizer Defendants no power to exclude Ranbaxy (or any other ANDA filer) from the United States market for atorvastatin calcium. No objectively reasonable litigant would have believed otherwise. The Pfizer Defendants and Ranbaxy both knew and believed this, as well.

105. In July 2000 and August 2001, the PTO issued the Process Patents.

106. Salts of atorvastatin are polymorphic, meaning that atorvastatin can exist in more than one form. Some of the atorvastatin polymorphs are crystalline while others are amorphous. Crystalline forms have different arrangements and/or conformations of the molecules in the crystal lattice. Amorphous forms consist of disordered arrangements of molecules that do not possess a distinguishable crystal lattice.

107. The '740 Patent issued from U.S. patent application no. 09/657,469 (the "'469 Application"). The '469 Application was a continuation of U.S. patent application No. 09/453,189, which was itself a continuation of U.S. patent application No. 08/983,369 (the " '369 Application"). The '369 Application issued as the '511 Patent. As a continuation of the '511

Patent, the '740 Patent has a virtually identical specification to the '511 Patent. Indeed, the Summary of the Invention sections of these two patents are identical, stating, in relevant part, as follows (emphasis added):

> [T]he present invention is a novel process for the preparation of amorphous atorvastatin and hydrates thereof which *comprises:*
>
> (a) dissolving ***crystalline Form I atorvastatin*** in a non-hydroxylic solvent; and
>
> (b) removing the solvent to afford amorphous atorvastatin.

108. The Process Patents are narrow in scope. For a generic manufacturer's process to infringe either of these patents, the generic manufacturer must, *inter alia,* start by dissolving *crystalline Form I atorvastatin* in the specified solvent. If the manufacturing process dissolves any crystalline form other than Form I in the specified solvent, or dissolves amorphous atorvastatin, the process does not and cannot infringe either of the Process Patents. The process must also meet each of the other claims of the Process Patents.

109. Because of the narrow scope of the Process Patents, and the ample number of amorphous and crystalline forms of atorvastatin that were available, a very large number of non-infringing alternatives existed to the technology claimed in the Process Patents. Indeed, the prior art, including the '893 Patent (covering the active ingredient of Lipitor, atorvastatin calcium), described numerous processes for making atorvastatin calcium that are prior art to the Process Patents and would invalidate the claims of the Process Patents if those claims read on the processes described in the '893 Patent.

110. The Pfizer Defendants themselves produced amorphous atorvastatin in their manufacturing processes before developing crystalline formulations such as Form I. There is no need for someone seeking to produce amorphous atorvastatin calcium to first produce Form I crystalline atorvastatin calcium.

111. The Pfizer Defendants were well aware that generic companies were seeking to develop generic versions of atorvastatin that did not infringe the Pfizer Defendants' patents, including the Process Patents. Indeed, it is common practice for experienced generic companies such as Ranbaxy to conduct patent searches during the drug development process, and to select drugs for further development that are covered by patents that the generic companies can readily design around.

112. Process patents are not required to be (and in fact cannot be) listed in the FDA's Orange Book, since they are not patents claiming an approved drug or an approved use of a drug. Therefore, the existence of the Process Patents did not create a regulatory impediment to generic entry, since ANDA filers are not required to file Paragraph IV certifications with respect to non-listed patents, and the Pfizer Defendants thus could not obtain an automatic 30-month stay of FDA approval of an ANDA by bringing a timely suit for infringement of the Process Patents.

113. Nor did the existence of the Process Patents create a legal impediment to generic entry. Because numerous non-infringing alternatives to the processes claimed in the Process Patents existed, there was no reasonable likelihood -- or any likelihood at all -- that the Pfizer Defendants would be able to use the Process Patents to obtain a court order enjoining ANDA filers, including Ranbaxy, from selling generic versions of Lipitor on the ground that they infringed the Process Patents.

114. Nevertheless, on or about March 24, 2008, the Pfizer Defendants filed a complaint in the United States District Court for the District of Delaware alleging that Ranbaxy infringed the Process Patents. The complaint contained only the most conclusory allegations of infringement. In particular, that complaint includes no factual allegations or support whatsoever establishing that Ranbaxy's process satisfied the various elements of the claims of the Process Patents, including

(but not limited to) the use of crystalline Form I at the start of the manufacturing process. The complaint merely states as follows:

> 30. Upon information and belief, Ranbaxy's Atorvastatin Product is made or is intended to be made by a process which if practiced in the United States would infringe the '511 patent.
>
> * * *
>
> 41. Upon information and belief, Ranbaxy's Atorvastatin Product is made or is intended to be made by a process which if practiced in the United States would infringe the '740 patent.

115. These allegations were completely baseless as a matter of fact and law. There was no basis for the Pfizer Defendants to believe that Ranbaxy was unaware of the elements of the Process Patents. Nor was there any basis to believe that Ranbaxy did not develop a manufacturing process that purposely avoided infringing on those patents. Indeed, as alleged above, there were numerous forms of atorvastatin, other than the crystalline Form I specified in the Process Patents, that Ranbaxy could have (and, upon information and belief, did) use at the start of its manufacturing process. And, there was no need for Ranbaxy to first create a crystalline form of atorvastatin calcium to manufacture an amorphous form of atorvastatin calcium.

116. Moreover, the Pfizer Defendants were well aware, prior to filing their complaint alleging that Ranbaxy infringed the Process Patents, that Ranbaxy intended to use amorphous atorvastatin as a starting material in manufacturing another generic atorvastatin drug, Caduet (a combination of Lipitor and another drug, Norvasc). The Pfizer Defendants had no basis to believe that Ranbaxy would not similarly use non-infringing amorphous atorvastatin, or another non-infringing form of atorvastatin, in its manufacturing process for its generic version of Lipitor. And there clearly would have been no reasonable basis to maintain the lawsuit alleging infringement of the Process Patents, if those lawsuits had been maintained absent the Agreement, as

the Pfizer Defendants would have definitively learned through discovery early in that case that Ranbaxy's manufacturing process did not infringe the Process Patents.

117. The Pfizer Defendants' complaint alleging infringement of their Process Patents did not cite to any facts or evidence whatsoever to support the Pfizer Defendants' conclusory assertion that Ranbaxy's process met any, let alone all, of the elements of the Process Patents.

118. When the Pfizer Defendants and Ranbaxy entered into the Agreement, Pfizer dismissed its complaint. During the pendency of the case, the Pfizer Defendants never produced any evidence to support their purely conclusory allegations that Ranbaxy infringed the Process Patents. Nor could they, since such allegations were false and baseless as a factual (and legal) matter.

119. As a result, the Process Patents had no exclusionary power vis-à-vis potential generic competitors, including Ranbaxy, because the Pfizer Defendants did not (and could not) prove the facts necessary to meet their burden of establishing infringement of each element of the Process Patents. Therefore, even though the Process Patents were presumed to be valid and enforceable, they had no exclusionary power because the Pfizer Defendants had no reasonable likelihood of meeting their burden of establishing that each element of those patents was infringed. In other words, the Pfizer Defendants could not use the Process Patents to exclude any generic competitor, including Ranbaxy, from the market.

120. Likewise, because Process Patents cannot be listed in the Orange Book, Pfizer could not (and did not) use the Process Patents to obtain an automatic 30-month stay of FDA approval of a pending ANDA.

**2. The "Unasserted Formulation Patents" and the '156 Patent**

121. At the time of the Agreement, the Pfizer Defendants also possessed other patents claiming particular forms of atorvastatin calcium, namely the Unasserted Formulation Patents (i.e., the '971 and '104 Patents) and the '156 Patent (which claimed crystalline forms of atorvastatin). Like the Process Patents, neither the Unasserted Formulation Patents nor the '156 Patent provided the Pfizer Defendants with any legitimate power to exclude Ranbaxy (or any other ANDA filer) from the relevant market, because the Pfizer Defendants could not have met their burden of establishing that Ranbaxy (or any other ANDA filer) infringed the Unasserted Formulation Patents nor the '156 Patent.

122. Both the '104 and '971 patents cover particular, and narrow, ways of formulating atorvastatin calcium with various excipients to stabilize the finished pharmaceutical product. Pfizer knew that potential generic competitors could design-around these narrow formulation patents and had in fact done so. Pfizer did not even attempt to assert either of these formulation patents against Ranbaxy or any other generic company seeking to enter the market.

123. Similarly, the '156 patent covered the crystalline form of atorvastatin calcium, not the amorphous form. Pfizer knew that Ranbaxy's product used an entirely different form -- the amorphous form. No reasonable litigant would have had any expectation of succeeding against Ranbaxy on a claim alleging infringement of the '971, '104 or '156 patents. The Pfizer Defendants did not have any realistic likelihood of obtaining a court order enjoining Ranbaxy (or any other ANDA filer) from selling its generic version of Lipitor based on infringement of the Unasserted Formulation Patents or the '156 Patent, something the Pfizer Defendants and Ranbaxy both knew and believed.

### 3. The Operation of the Agreement

124. Pursuant to the Agreement, Ranbaxy agreed not to sell generic Lipitor in the United States until November 30, 2011 -- more than twenty (20) months after expiration of the '893 patent and five (5) months after the '995 Patent was expected to expire if Pfizer succeeded in getting it reissued.

125. Ranbaxy agreed to keep its generic version of Lipitor off the market until well after the legitimate exclusionary power of the Pfizer Defendants' patents had expired because it was paid handsomely not to compete with the Pfizer Defendants. As explained above, Ranbaxy received at least the following financial compensation in exchange for its agreement to delay coming to market with its generic version of Lipitor in the United States: (1) the effective forgiveness of Pfizer's damage claim against Ranbaxy on the separate product quinapril hydrochloride (Accupril) that Ranbaxy had launched at risk; and (2) permission to sell generic versions of Lipitor in at least eleven foreign markets, including Vietnam, Malaysia, Canada, Belgium, the Netherlands, Germany, Sweden, Italy, and Australia.

126. As part of the Agreement, Ranbaxy also agreed not to challenge the validity of any Lipitor patent, including the '995 Patent, that was at the time the subject of reissuance proceedings. Pursuant to this Agreement, Ranbaxy dropped its challenge to the reissuance of the '995 Patent -- a challenge that had been successful prior to the date of the Agreement.

127. In January 2007, in the wake of the 2006 Federal Circuit ruling invalidating the vital Claim 6 of the '995 Patent on technical grounds, Pfizer sought reissuance of the '995 Patent from the PTO "to correct a technical defect in some of the patent claims." In doing so, Pfizer sought to limit the PTO's review to a determination of whether the newly redrafted claims (to correctly construct dependent or independent claims) would satisfy the applicable patent construction rules.

128. While Pfizer sought only to correct a technical defect, it knew that it potentially faced significant hurdles with respect to the validity of the '995 Patent. It knew that the PTO or others might raise the far more substantive problem that the '995 Patent was simply an obvious extension of the original '893 Patent (and that the data to support a finding of surprising or unexpected activity of the enantiomer was false). By this time in early 2007, the '995 Patent and its nearly identical foreign counterparts had been the subject of considerable litigation, not only in the federal district court *Ranbaxy* proceeding (with its limited scope of appellate review), but also in other countries throughout the world. In the original patent prosecution, Pfizer argued that biological data showed that that the R-trans enantiomer of atorvastatin was ten times more active than racemic atorvastatin. But by the time that it sought the reissuance of the patent, foreign patent proceedings had established that the biological data was false and that the R-trans enantiomer of atorvastatin was no more active than the expected activity of twice that of the racemate. As a result, in communications with the PTO during the reissue proceedings, Pfizer expressly disavowed the reliability of the 1989-1993 biological data as a basis to reissue any of the claims in the '995 Patent.

129. On January 16, 2007, Dr. Roth and the Pfizer Defendants submitted a reissue application for claim 6 of the '995 Patent. The applicants did not amend or modify the '995 Patent specification as part of the reissue proceedings. Dr. Roth's remarks included a list of the "objective evidence" that "completely refutes any suggestion of obviousness." But the list did **not** include the purported surprising effectiveness of the R-trans enantiomer or a purported ten times greater activity of the R-trans enantiomer than the racemate.

130. An Informational Disclosure Statement of the same date states:

> Subsequent to the Federal Circuit's decision, while preparing for trial in Australia on a '995 counterpart, Pfizer first learned of **significant errors** in the COR results

> which neither Pfizer nor the parties adverse to it had discovered before. This discovery led Pfizer to advise the Federal Circuit that COR data could not be relied on to compare the relative activity of compounds — see Exhibit 9, page 10, fn 2. Thus **any earlier reference in Pfizer's findings, conclusions and brief to relative activity among compounds based on the COR test is withdrawn and is not relied on in these reissue proceedings. Pfizer does not at this point in the reissue rely for patentability on any comparisons based on CSI.** Neither CSI nor COR data were relied on by either U.S. court in reaching their decisions regarding the validity of '995 claim 6.

The Pfizer Defendants similarly stated: "Pfizer does not now rely on any . . . data [comparing between and among calcium salts and other salts of atorvastatin and its racemates] in support of patentability."

131. On June 7, 2007, as part of reissue proceedings on the '995 Patent, the Pfizer Defendants submitted a Second Informational Disclosure Statement that discusses "Foreign Proceedings on '995 Counterparts" and attached additional materials produced as part of certain non-U.S. proceedings. The Pfizer Defendants acknowledged therein that the biological data submitted in support of their patent applications -- in the CSI Table, the Roth Declaration, and the foreign "'995 counterparts" -- was inaccurate (emphasis added):

> [A]pplicant is submitting these documents to permit the Examiner to consider their potential materiality. Further, many of these documents . . . contain biological data or summaries of biological data, and **some of that biological data is now understood to be inaccurate** (due to transcription errors, calculation errors, experimental errors, etc.). Applicant is not submitting **corrected** biological data at the present time because, as applicant has emphasized repeatedly in these reissue proceedings, applicant is not currently relying on the biological data for patentability.

132. Elsewhere in the reissue proceedings, Dr. Roth and the other Pfizer Defendants referred to the biological data at issue in the Australian and Canadian patent litigation as "biologic data that Pfizer **then** argued showed that the atorvastatin enantiomer had unexpected and surprising inhibition of cholesterol biosynthesis in-vitro in comparison to the racemic form of atorvastatin," while reiterating that they "**are not relying on any of the biological data as a basis for the**

**patentability of the pending claims at the present time."** Similarly, Dr. Roth and the other Pfizer Defendants stated, "[a]pplicant is not submitting **corrected** biological data at the present time because, as applicant has emphasized repeatedly in these reissue proceedings, applicant is not currently relying on the biological data for patentability."

133. At one point in the reissue proceedings, the examiner made a mistake and relied on the biological data to overcome an obviousness rejection:

> Claims 6, 13 and 14 have not been rejected as being obvious as the declaration of Bruce D. Roth filed February 25, 1991 discloses unexpected properties which would overcome any 35 USC 103(a) rejection of claims 6, 13 and 14 as atorvastatin calcium was shown to have activity greater than fifty-fold more than that of the S-trans and at least ten-fold more than that of the racemate.

197. Pfizer knew it could no longer allow the PTO to use its falsified biological data. As a result, it "reiterated [to the PTO] that they are not presently relying on any of the biological data (including the data contained in the Roth Declaration) as support for the patentability of claims 6, 13 and 14." It stated:

> Although applicant believes that the evidence provided in the Roth Declaration is sound, and is in no way disclaiming this data, it does not believe that it is necessary to consider such evidence in view of the present record . . . applicant respectfully requests that the Examiner withdraw her reliance on the data in the Roth Declaration and focus instead on the overwhelming evidence of secondary considerations that are discussed above.

The referenced secondary considerations included an argument based on Lipitor's commercial success.

134. On April 24, 2008, the PTO issued a non-final rejection of claims 6, 13, and 14. In so doing, the Examiner stated, "[a]s the data contained in the Roth declaration has not been relied on by Applicant in the instant reissue and is not a comparison of the claimed subject matter (atorvastatin calcium) to the closest prior art, the examiner withdraws the reliance on the data in the Roth Declaration to overcome an obviousness rejection of reissue claims 6, 13 and 14." Instead,

the Examiner relied on secondary considerations identified by the Applicants, namely Lipitor's commercial success.

135. Around this same time, Pfizer and Ranbaxy were negotiating the Agreement. As a part of that June 2008 Agreement, Ranbaxy agreed to withdraw its challenge to the reissuance of the '995 Patent.

136. Free of Ranbaxy's challenge, Pfizer was able to convince the PTO to reissue claims 6, 13, and 14 of the '995 Patent as the '667 Patent on April 6, 2009. The PTO based its ruling to grant the re-issuance of the '995 Patent not on the basis of the biological studies and representations made by Warner-Lambert (even though a version of the CSI assay data remains in the specification for the patent), but instead on the basis of the Pfizer Defendants' arguments that the commercial success of Lipitor shows that the '995 Patent could not have been obvious.

137. The '667 Patent, like the '995 Patent, was expected to expire (and did expire) on June 28, 2011. Nevertheless, pursuant to the Agreement, which provided Ranbaxy with substantial compensation in exchange for its agreement not to compete, Ranbaxy could not sell its generic version of Lipitor until November 30, 2011, a full five months after the '667 Patent expired.

138. The Agreement was unlawful because it constituted an illegal reverse-payment market allocation agreement, pursuant to which Pfizer gave substantial financial inducements to its competitor, Ranbaxy, in exchange for Ranbaxy's agreement to allocate the entire United States market for atorvastatin calcium to Pfizer through November 30, 2011.

### G. In Furtherance of the Agreement, the Pfizer Defendants Thwarted Other ANDA Filers from Triggering Ranbaxy's 180-Day First-to-File Marketing Exclusivity

139. The Agreement sought to prevent other ANDA filers from launching their own generic versions of Lipitor before Ranbaxy. Ranbaxy's anticipated 180-day marketing exclusivity

as the first filer of a generic Lipitor ANDA meant that only Ranbaxy's own first commercial marketing of its ANDA product would trigger the 180-day period. Before the expiration of that 180-day period, other generic Lipitor ANDA filers could not market their generic versions of Lipitor.

140. Other ANDA filers could trigger Ranbaxy's 180-day exclusivity by obtaining one or more court decisions that the patents listed in the FDA "Orange Book" as claiming Lipitor are invalid or not infringed. If another ANDA filer were to obtain such a court decision, Ranbaxy's 180-day first-to-file marketing exclusivity would commence running, even if Ranbaxy had not yet begun commercial marketing of its ANDA product by that time, and even if Ranbaxy did not want its exclusivity to commence running.

141. Another way that other ANDA filers could circumvent Ranbaxy's 180-day exclusivity was by convincing the FDA to deprive Ranbaxy of its 180-day exclusivity period and approve the ANDAs of other generic companies unimpeded by any 180-day period.

142. These two possibilities were of substantial concern to the Pfizer Defendants and Ranbaxy in 2008 when they entered into the Agreement. The Pfizer Defendants did not want generic Lipitor competition earlier than the November 30, 2011 date provided in the Agreement, and Ranbaxy did not want any involuntary triggering or forfeiture of its anticipated, and enormously valuable, 180-day first-to-file marketing exclusivity. Such events would frustrate the Agreement, and threaten to diminish or eliminate the value of Ranbaxy's exclusivity. Both the Pfizer Defendants and Ranbaxy had a keen interest in ensuring that Ranbaxy's 180-day exclusivity was protected, to prevent other ANDA applicants for generic Lipitor from coming to market.

143. Therefore, to prevent the involuntary triggering of Ranbaxy's 180-day first-to-file marketing exclusivity prior to November 30, 2011, the Pfizer Defendants, pursuant to, and in

furtherance of, the Agreement, engaged in a sustained campaign to thwart the efforts of generic manufacturers to obtain judgments of invalidity and/or non-infringement with respect to the Pfizer's Lipitor patents.

144. To effectuate this campaign, the Pfizer Defendants settled cases prior to judgments on the merits, vigorously opposed the efforts of ANDA applicants to obtain declarations that the Unasserted Formulation Patents were invalid and/or not infringed, and otherwise engaged in a pattern of dilatory conduct designed to forestall, prior to Ranbaxy's agreed-upon November 30, 2011 entry date, judicial decisions that the Unasserted Formulation Patents were invalid and/or not infringed.

**1. Apotex**

145. For instance, after it received a Paragraph IV certification in December of 2008 from Apotex, Inc. and Apotex Corporation ("Apotex") as to the '995 Patent, the Unasserted Formulation Patents, and the '156 Patent, the Pfizer Defendants sued Apotex for infringement of only the '995 Patent. Apotex's answer included counterclaims, pursuant to 21 U.S.C. § 355(j)(5)(C), asserting non-infringement and invalidity of the '995 Patent (and '667 reissue Patent), the Unasserted Formulation Patents, and the '156 Patent.

146. As the Apotex trial court recognized: "Apotex's hope is to obtain a decision from this Court that the Unasserted Patents are invalid or are not infringed by Apotex's product, thereby triggering Ranbaxy's exclusivity period. Absent such a court ruling (either in this case or in litigation involving another subsequent ANDA filer), Apotex will not be able to market its generic atorvastatin drug until 180 days after Ranbaxy begins marketing its drug, which, as a result of the settlement agreement between Pfizer and Ranbaxy, will not occur until November 2011 at the earliest."

147. In furtherance of the Agreement, the Pfizer Defendants sought dismissal of Apotex's counterclaims, arguing that they were nonjusticiable.

148. Although the Apotex court denied the Pfizer Defendants' motion to dismiss, the motion had its intended effect: it delayed discovery and litigation for well over a year and, combined with subsequent litigation delay tactics surrounding discovery and summary judgment motions, prevented Apotex from obtaining a judgment of non-infringement and invalidity of the Unasserted Formulation Patents and the '156 Patent before November 30, 2011.

**2. Mylan**

149. On May 1, 2009, Mylan sent the Pfizer Defendants a letter providing notice of Mylan's ANDA submission and intent to market a generic version of Lipitor, supplying a Paragraph IV certification as to the Unasserted Formulation Patents and the '156 Patent, and offering confidential access to certain portions of Mylan's ANDA. By June 15, 2009, the Pfizer Defendants had filed an action against Mylan alleging infringement of only the '156 Patent, and seeking a declaratory judgment of infringement of the Process Patents.

150. Mylan filed a motion for leave to file an amended answer containing counterclaims pertaining to the Unasserted Formulation Patents, to obtain a declaration of noninfringement and/or invalidity with respect to them. In support of that effort, Mylan sought discovery regarding the Unasserted Formulation Patents. Mylan's motion to compel discovery was granted by court order on August 25, 2010.

151. But the Pfizer Defendants continued to refuse to supply Mylan with the discovery it required. Mylan was forced to file an emergency motion to enforce the court's discovery order.

152. To try to sabotage Mylan's continued efforts to obtain discovery and thus proceed with its counterclaims pertaining to the Unasserted Formulation Patents, the Pfizer Defendants, on

August 30, 2010, hastily covenanted not to sue Mylan, hoping to moot Mylan's continued efforts to discover facts that would assist its counterclaims and the court's order of August 25, 2010 compelling that discovery.

153. The court expressed frustration with the Pfizer Defendants' litigation tactics regarding the Unasserted Formulation Patents, and enforced its order requiring the Pfizer Defendants to supply discovery to Mylan pertaining to the Unasserted Patents:

> I'm granting Mylan's request. I'm very troubled by the conduct of Pfizer here with respect to this ongoing discovery dispute. The way I see it, if Pfizer wanted to provide a covenant not to sue, it was within its authority at any time to provide the covenant not to sue with respect to the formulation patents. For whatever reasoning only known to Pfizer, they waited until August 30th [2010] to give the covenants not to sue, which was perhaps not coincidently shortly after the issuance of the August 25th order granting the defendants' request for discovery. . . . That's simply just not how this is supposed to work.

154. The Pfizer Defendants continued to delay the progress of the case. In a November 20, 2010 letter to the court regarding Dr. Reddy's Laboratories Ltd.'s ("DRL") request to be heard at the *Markman* hearing in the Mylan patent litigation pertaining to the '156 Patent, counsel for Mylan complained about the Pfizer Defendants' continued dilatory tactics: "Pfizer uses DRL's request to be heard on the '156 patent as another opportunity to attempt to delay the Pfizer-Mylan cases."

155. Mylan also sought to remove Ranbaxy's blocking 180-day exclusivity period by way of a separate action against the FDA seeking an order requiring the FDA to determine whether or not Ranbaxy was entitled to a 180-day first-to-file marketing exclusivity.

**3. Actavis**

156. In August of 2010, the Pfizer Defendants sued Actavis Group hf, Actavis Inc., Actavis Elizabeth LLC and Actavis Pharma Manufacturing Private Ltd. (collectively "Actavis") after Actavis submitted to the FDA an ANDA seeking approval to market generic Lipitor.

Although Actavis had included the Unasserted Formulation Patents in its Paragraph IV certification, the Pfizer Defendants sued Actavis only for infringement of the '156 Patent.

157. In September 2010, Actavis counterclaimed for declaratory judgment of invalidity and non-infringement of the Unasserted Formulation Patents. The Pfizer Defendants moved to dismiss these counterclaims as unripe. In opposing that motion, Actavis argued that "Pfizer's listing of the [Unasserted Formulation Patents] in the Orange Book and its refusal to litigate them creates patent uncertainty and indefinitely delays the approval of Actavis' ANDA," and noted that "[e]ven if Pfizer granted Actavis a covenant not to sue on the [Unasserted Formulation Patents], however, it would not address the fact that Actavis is suffering from an indefinite delay in FDA approval of its ANDA and its concurrent inability to enter the market."

158. Actavis also argued that, by virtue of the Pfizer Defendants' Agreement with Ranbaxy and its refusal to litigate the validity and infringement of its Unasserted Formulation Patents, "Actavis is being restrained from the free exploitation of non-infringing goods, it is suffering exactly the type of injury-in-fact that is sufficient to establish Article III standing" (internal citations and quotations omitted).

159. Despite their efforts to do so, no ANDA filer was able to circumvent the Agreement between the Pfizer Defendants and Ranbaxy by triggering Ranbaxy's 180-day marketing exclusivity prior to November 30, 2011.

### H. Ranbaxy's ANDA Would Have Been Approved Earlier Absent Defendants' Anticompetitive Scheme

160. Ranbaxy's atorvastatin calcium ANDA would have received final approval earlier absent the Defendants' anticompetitive conduct. The FDA has policies and procedures in place to prioritize the review of ANDAs, *e.g.*, expediting the review of the first applications for which there are no blocking patents or exclusivities. Regarding the FDA's review of applications for generic

Lipitor, the Agreement blocked the applicants, including Ranbaxy, from marketing their products. The FDA was aware that the earliest date that Ranbaxy could market generic Lipitor under its Agreement with Pfizer was November 30, 2011. As Ranbaxy maintained the 180-day exclusivity, all subsequent applicants were blocked from marketing generic Lipitor as well, until Ranbaxy's exclusivity was triggered and had expired.

161. Furthermore, the FDA was under tremendous pressure, including from Congress, to speed consumer access to generic Lipitor at the earliest possible moment. Ranbaxy was also under tremendous pressure to monetize its biggest asset, *i.e.*, its first-to-file atorvastatin ANDA, at the earliest possible moment, so much so that Ranbaxy paid Teva a large amount of money -- in effect an insurance policy -- to ensure that Ranbaxy would be able to launch generic Lipitor at the earliest possible moment.

162. As it turned out, Ranbaxy was granted final approval on November 30, 2011, *i.e.*, it was able to launch on the earliest date under the Agreement with the Pfizer Defendants. Ranbaxy shipped generic Lipitor slightly in advance of that date, under "quarantine" agreements with wholesalers. Had the Agreement permitted an earlier entry date, or had there been no such Agreement at all, generic Lipitor could have been, and would have been, marketed earlier than November 30, 2011, because the FDA would have granted final approval earlier and Ranbaxy would have launched earlier.

**1. The Longstanding FDA Policy of Prioritizing the Review of ANDAs**

163. As a matter of procedure and practice, the FDA has long prioritized its review of pending applications. For example, in 1990, the Division of Generic Drugs within the FDA issued a policy and procedure guide establishing a "first-in, first-reviewed" policy for generic drug applicants. This policy, along with similar guidance for the pharmaceutical industry, has been

updated and modified from time to time and is still in place today. One of the modifications that has been instituted over the years is to prioritize the review of the first ANDAs for which there is no blocking patent or exclusivity.

164. Similarly, the FDA has been experiencing a backlog of pending applications, such that prioritizing ANDA review is more important than ever. As a matter of procedure and practice, in a situation where an ANDA filer will not be able to market a drug until a time far into the future, such as Ranbaxy's generic Lipitor ANDA due to the Agreement, the FDA shifts assets to other priorities within the Office of Generic Drugs. The FDA prioritizes the review of ANDAs in this way by keeping abreast of the current posture of any litigation that may impact the timing of an ANDA approval. For instance, as a matter of procedure and practice, upon accepting an ANDA for filing, the FDA expressly requests that the applicant promptly submit a copy of any settlement agreement between the applicant and the patent holder.

**2. The FDA's Review of Ranbaxy's ANDA for Atorvastatin Calcium**

165. On June 18, 2008, Ranbaxy announced the Agreement in which Ranbaxy's launch date was delayed until November 30, 2011. Ranbaxy submitted this information to the FDA shortly thereafter.

166. Thus, due to the FDA's longstanding policy of prioritizing the review of ANDAs and the recent pressure of the ANDA backlog, on information and belief, once the FDA learned of the fact that the first generic for Lipitor, *i.e.*, Ranbaxy, would not be marketed until November 30, 2011, the FDA shifted assets away from Ranbaxy's ANDA and the Petition and toward other priorities within the FDA until the November date drew closer.

### 3. The Tremendous Pressure on the FDA to Approve Generic Lipitor

167. That the FDA was under immense pressure to approve a generic Lipitor product also shows that it would have earlier approved Ranbaxy's ANDA absent the agreed-to date for Ranbaxy's market entry contained in the Agreement.

168. For example, on March 10, 2011, Senate Health, Education, Labor, and Pensions Committee Chairman Tom Harkin, along with Senators Jay Rockefeller, Charles Schumer, Debbie Stabenow, and Sherrod Brown sent a letter to FDA Commissioner Dr. Margaret Hamburg. In the letter, the Senators stated: "Given the tremendous savings that access to generic atorvastatin will afford both consumers and the government, we urge you to act now to clarify the relevant regulatory issues in the matter so the public can receive access to a more affordable generic version of Lipitor on the earliest possible date." The "tremendous savings" to consumers and the government would be between "$3.97 billion to $6.7 billion a year upon generic entry, which equates to $10.9 million to $18.3 million a day." Likewise, the FDA recognized the importance and cost savings of having a generic Lipitor available to consumers.

### 4. The Tremendous Pressure on Ranbaxy to Market a Generic Lipitor and/or Otherwise Monetize its First-To-File Exclusivity

169. Ranbaxy, too, was motivated to monetize its first-to-file 180-day marketing exclusivity and would have more rapidly pursued its atorvastatin calcium ANDA absent the agreed-to date for market entry in the Agreement.

170. The first-to-file generic Lipitor was a tremendous opportunity for Ranbaxy. With only a month of generic Lipitor sales in 2011, atorvastatin calcium was Ranbaxy's largest selling product in 2011. Ranbaxy also achieved sales growth of 17% over the previous year, "mainly on account of revenues from First to File product, Atorvastatin, in the US market in December 2011."

171. In order to capitalize on the first to file opportunity, Ranbaxy took steps to insure that issues related to its good manufacturing practices did not prevent it from being able to market generic Lipitor. For instance, on information and belief, in December 2009, Ranbaxy effectuated a manufacturing site transfer of atorvastatin calcium from its facility in India to Ranbaxy's wholly-owned subsidiary, Ohm Laboratories in New Jersey. Whatever issues Ranbaxy may have been having with FDA regulatory compliance at one or more of its facilities in India did not affect the Ohm facility in New Jersey. This is borne out by the fact that Ranbaxy ultimately received approval to market generic Lipitor in the U.S. from the Ohm facility in New Jersey.

172. Absent the Defendants' anticompetitive scheme, Ranbaxy could and would have proceeded with a manufacturing site transfer earlier, either to Ohm or to another facility. On information and belief, the Ohm facility had been operational for Ranbaxy for quite some time and was available to take over manufacturing of generic atorvastatin calcium pursuant to a site transfer at any time during the relevant time period at issue here.

173. In fact, at or around the same time that Ranbaxy filed its ANDA for atorvastatin calcium, Ranbaxy also filed the first ANDA to market a generic version of simvastatin, a drug in the same "statin" family as atorvastatin calcium. On information and belief, as with atorvastatin, Ranbaxy effectuated a manufacturing site transfer for simvastatin from India to the Ohm facility in New Jersey. Ranbaxy received final approval for its simvastatin ANDA on June 23, 2006 and began marketing its first-to-file generic shortly thereafter.

174. Similarly, on information and belief, in the same time period as the atorvastatin calcium filing, Ranbaxy filed the first ANDA with the FDA to market donepezil hydrochloride. Donepezil hydrochloride is the active ingredient in Aricept. On information and belief, Aricept had approximately $2.6B in sales in 2010. On information and belief, around the time of the

atorvastatin calcium site transfer in December 2009, Ranbaxy effectuated a site transfer of donepezil hydrochloride from India to the Ohm facility in New Jersey. On information and belief, on the first day a generic could be marketed, November 26, 2010, Ranbaxy received approval with first-to-file exclusivity to market donepezil hydrochloride. In 2011, donepezil was the second best performing product after atorvastatin calcium.

175. Finally, on information and belief, Ranbaxy and Teva entered into an agreement to insure that Ranbaxy was able to benefit from its first-to-file status. Negotiations between Ranbaxy and Teva regarding generic Lipitor began in 2009. On information and belief, Ranbaxy and Teva discussed three possible ways of monetizing Ranbaxy's first to file ANDA: (1) a manufacturing site transfer from Ranbaxy's facility in India to Teva, under which Teva would pay Ranbaxy a lump sum transfer fee and royalties on sales of generic Lipitor; (2) a simultaneous launch of generic Lipitor by Ranbaxy and Teva; and (3) a manufacturing site transfer from India to Ranbaxy's Ohm facility in New Jersey, Ranbaxy's return to Teva of the lump sum transfer fee, and Ranbaxy's payment of a portion of its profits on generic Lipitor to Teva. In 2010, Ranbaxy and Teva signed an agreement regarding generic Lipitor containing some or all of these options and/or other options.

176. Once Ranbaxy made the decision to partner with another company in order to monetize generic Lipitor, it is hardly surprising that Ranbaxy chose Teva. It is well known in the industry that Teva looks to partner with 180-day exclusivity holders given the profit opportunity such exclusivities present.

177. Since Ranbaxy gained approval to market generic Lipitor from its Ohm facility in New Jersey, on information and belief, it never needed the insurance policy that the deal with Teva effectively provided. However, Ranbaxy still paid Teva a substantial amount of money to insure

that it would be able to monetize its first-to-file atorvastatin calcium ANDA at the earliest possible moment under the Agreement

## VI. TRADE AND COMMERCE

178. Defendants' efforts to monopolize and restrain competition in the market for atorvastatin calcium have substantially affected interstate commerce.

179. At all material times, the Pfizer Defendants manufactured, promoted, distributed, and sold substantial amounts of branded Lipitor in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States. Beginning around November 30, 2011, Ranbaxy did the same with respect to generic Lipitor.

## VII. MONOPOLY POWER AND MARKET DEFINITION

180. At all relevant times, the Pfizer Defendants had monopoly power over atorvastatin calcium because they had the power to maintain the price of atorvastatin calcium at supracompetitive levels without losing substantial sales.

181. A small but significant, non-transitory price increase by the Pfizer Defendants with respect to Lipitor would not have caused a significant loss of sales.

182. Lipitor does not exhibit significant, positive cross-elasticity of demand with respect to price, with any product other than AB-rated generic versions of Lipitor.

183. Because of, among other reasons, its use and varying ability to inhibit the production of cholesterol, Lipitor is differentiated from all products other than AB-rated generic versions of Lipitor.

184. The Pfizer Defendants needed to control only Lipitor and its AB-rated generic equivalents, and no other products, in order to maintain the price of Lipitor profitably at supracompetitive prices. Only the market entry of a competing, AB-rated generic version of

Lipitor would render the Pfizer Defendants unable to profitably maintain their current prices of Lipitor without losing substantial sales.

185. The Pfizer Defendants also sold branded Lipitor at prices well in excess of marginal costs, and in excess of the competitive price, and enjoyed high profit margins.

186. Defendants have had, and exercised, the power to exclude generic competition to branded Lipitor.

187. Defendants, at all relevant times, enjoyed high barriers to entry with respect to branded and generic Lipitor.

188. To the extent that Plaintiffs are legally required to prove monopoly power circumstantially by first defining a relevant product market, Plaintiffs allege that the relevant market is all atorvastatin calcium products -- *i.e.*, Lipitor (in all its forms and dosage strengths) and AB-rated bioequivalent atorvastatin calcium products. During the period relevant to this case, Defendants have been able to profitably maintain the price of Lipitor well above competitive levels.

189. The relevant geographic market is the United States and its territories.

190. The Pfizer Defendants' market share in the relevant market was 100% until the entry of generic atorvastatin calcium in late November 2011.

## VIII. MARKET EFFECTS

191. Ranbaxy began to ship generic Lipitor on or shortly before November 29, 2011, prior to receiving formal, written final approval of its ANDA from the FDA. Ranbaxy informed its customers that such shipments of generic Lipitor were subject to "quarantine," meaning that the generic Lipitor could not be resold until the FDA's issuance to Ranbaxy of formal, written ANDA approval.

192. The FDA purposely waited to issue formal written approval for Ranbaxy's ANDA until November 30, 2011, because the FDA knew that the Agreement prevented Ranbaxy from selling generic Lipitor until November 30, 2011. Ranbaxy's ANDA was in an approvable condition well before November 30, 2011 and, were it not for the Agreement, would have received final FDA approval at an earlier time. The FDA organizes its priorities around "rate limiters," and the Agreement was a rate limiter that caused the FDA to wait until November 30, 2011 to issue formal, written approval to Ranbaxy's ANDA.

193. The acts and practices of Defendants had the purpose and effect of unreasonably restraining and injuring competition by protecting Lipitor from generic competition for a substantial period of time until November 30, 2011. Defendants' actions allowed the Pfizer Defendants to maintain a monopoly and exclude competition in the market for atorvastatin calcium, to the detriment of Plaintiffs.

194. In the absence of some or all of Defendants' anticompetitive scheme, Ranbaxy or one or more other generic competitors would have begun selling AB-rated generic versions of Lipitor much sooner than November 30, 2011, when Ranbaxy launched. Specifically, in the absence of some or all of Defendants' anticompetitive scheme, Ranbaxy or one or more generic competitors would have launched generic Lipitor earlier.

195. Ranbaxy and the other ANDA applicants seeking to market generic Lipitor had extensive experience in the pharmaceutical industry, including in obtaining approval for ANDAs, manufacturing commercial launch quantities adequate to meet market demand, marketing generic pharmaceutical products, and paying and receiving consideration for selective waiver and/or relinquishment of 180-day first-to-file marketing exclusivities.

196. As a result of the delay in generic Lipitor competition brought about by Defendants' anticompetitive scheme, in whole or in part, Plaintiffs paid more to acquire atorvastatin calcium than they would have paid absent Defendants' illegal conduct.

197. Typically, generic versions of brand-name drugs are initially priced significantly below the corresponding branded drug to which they are AB-rated. As a result, upon generic entry, some or all of the direct purchases of branded drugs are rapidly substituted for generic versions of the drug. As more generic manufacturers enter the market, prices for generic versions of a drug predictably plunge even further because of competition among the generic manufacturers, and, correspondingly, the brand name drug continues to lose even more market share to the generics.

198. This price competition enables all direct purchasers of the drugs to: (a) purchase generic versions of a drug at a substantially lower price, and/or (b) purchase the brand name drug at a reduced price. Consequently, brand name drug manufacturers have a keen financial interest in delaying the onset of generic competition, and purchasers experience substantial cost inflation from that delay.

199. If generic Lipitor competitors had not been unlawfully prevented from earlier entering the market and competing with the Pfizer Defendants, Plaintiffs would have paid less for atorvastatin calcium by (a) substituting purchases of less-expensive AB-rated generic Lipitor for their purchases of more-expensive branded Lipitor, (b) receiving discounts on their remaining branded Lipitor purchases, and (c) purchasing generic Lipitor at lower prices sooner.

200. Moreover, due to Defendants' conduct, other generic manufacturers were discouraged from and/or delayed in developing generic versions of Lipitor.

201. Thus, Defendants' unlawful conduct deprived Plaintiffs of the benefits of competition that the antitrust laws were designed to ensure.

## IX. ANTITRUST IMPACT

202. During the relevant period, Plaintiffs (or their assignor) purchased substantial amounts of Lipitor from the Pfizer Defendants. After generic entry, Plaintiffs purchased substantial amounts of generic atorvastatin. As a result of Defendants' illegal conduct, Plaintiffs were compelled to pay, and did pay, artificially inflated prices for their atorvastatin calcium requirements. Those prices were substantially greater than the prices that would have been paid absent the illegal conduct alleged herein, because: (1) the price of brand-name Lipitor was artificially inflated by Defendants' illegal conduct, and/or (2) Plaintiffs were deprived of the opportunity to purchase lower-priced generic Lipitor sooner.

203. As a consequence, Plaintiffs have sustained substantial losses and damage to their business and property in the form of overcharges. The full amount and forms and components of such damages will be calculated after discovery and upon proof at trial.

## X. CLAIMS FOR RELIEF

### CLAIM I: VIOLATION OF 15 U.S.C. § 2
### (MONOPOLIZATION AND MONOPOLISTIC SCHEME)

204. Plaintiffs hereby incorporate by reference the allegations contained in paragraphs 1 through 203 above. This claim is asserted against the Pfizer Defendants only.

205. At all relevant times, the Pfizer Defendants possessed substantial market power (*i.e.*, monopoly power) in the relevant market. The Pfizer Defendants possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

206. Through the anticompetitive scheme, as alleged extensively above, the Pfizer Defendants willfully maintained their monopoly power in the relevant market using restrictive or exclusionary conduct, rather than by means of greater business acumen, and injured Plaintiffs thereby.

207. It was the Pfizer Defendants' conscious object to further their dominance in the relevant market by and through the anticompetitive scheme.

208. As a direct and proximate result of the Pfizer Defendants' illegal and monopolistic conduct, as alleged herein, Plaintiffs suffered antitrust injury as alleged above.

## CLAIM II: VIOLATION OF 15 U.S.C. § 1 (CONSPIRACY IN RESTRAINT OF TRADE)

209. Plaintiffs hereby incorporate by reference the allegations contained in paragraphs 1 through 203 above. This claim is asserted against all Defendants.

210. In 2008, the Pfizer Defendants and Ranbaxy entered into the Agreement. The Agreement is and was a contract, combination and/or conspiracy that substantially, unreasonably, and unduly restrained trade in the relevant market, the purpose and effect of which was to: (a) allocate all sales of atorvastatin calcium in the United States to the Pfizer Defendants until November 30, 2011; (b) prevent the sale of any generic version of atorvastatin calcium in the United States until November 30, 2011; and (c) fix the price which Plaintiffs would pay for atorvastatin calcium.

211. The Agreement, and Defendants' actions pursuant to the Agreement, harmed Plaintiffs as set forth above.

212. There is and was no legitimate, nonpretextual, procompetitive business justification for the Agreement that outweighs its harmful effect. Even if there was some conceivable justification, the Agreement is and was broader than necessary to achieve such a purpose.

213. As a direct and proximate result of the Pfizer Defendants' and Ranbaxy's anticompetitive conduct, as alleged herein, Plaintiffs suffered antitrust injury as alleged above.

**CLAIM III: VIOLATION OF 15 U.S.C. § 2**
**(CONSPIRACY TO MONOPOLIZE)**

214. Plaintiffs hereby incorporate by reference the allegations in paragraphs 1 through 203 above. This claim is asserted against all Defendants.

215. Through the anticompetitive scheme, as alleged extensively above, the Pfizer Defendants and Ranbaxy conspired to maintain and enhance the Pfizer Defendants' monopoly power in the relevant market.

216. The Pfizer Defendants and Ranbaxy knowingly and intentionally conspired to maintain and enhance the Pfizer Defendants' monopoly power in the relevant market.

217. The Pfizer Defendants and Ranbaxy specifically intended that the anticompetitive scheme would maintain the Pfizer Defendants' monopoly power in the relevant market, and injured Plaintiffs thereby.

218. The Pfizer Defendants and Ranbaxy each committed at least one overt act in furtherance of the conspiracy.

219. As a direct and proximate result of the Pfizer Defendants' and Ranbaxy's illegal and monopolistic conduct, Plaintiffs suffered antitrust injury as alleged above.

**CLAIM IV: VIOLATION OF 15 U.S.C. § 2**
**(ATTEMPTED MONOPOLIZATION)**

220. Plaintiffs hereby incorporate by reference the allegations in paragraphs 1 through 203 above. This claim is asserted against the Pfizer Defendants only.

221. The Pfizer Defendants, through their anticompetitive scheme, specifically intended to maintain monopoly power in the relevant market. It was the Pfizer Defendants' conscious objective to control prices and/or to exclude competition in the relevant market.

222. The natural and probable consequence of the Pfizer Defendants' anticompetitive scheme, which was intended by, and plainly foreseeable to, the Pfizer Defendants, was to control prices and exclude competition in the relevant market, to the extent that it did not succeed.

223. There was a substantial and real chance, a reasonable likelihood, and/or a dangerous probability that the Pfizer Defendants would succeed in and achieve its goal of maintaining monopoly power in the relevant market.

224. As a direct and proximate result of the Pfizer Defendants' illegal and monopolistic conduct, Plaintiffs suffered antitrust injury as alleged above.

## XI. DEMAND FOR JUDGMENT

WHEREFORE, Plaintiffs pray for judgment against Defendants and for the following relief:

A. Joint and several judgments against Defendants and in favor of Plaintiffs;

B. An award to Plaintiffs of three times their actual damages, as determined by a jury trial;

C. Permanent injunctive relief enjoining Defendants from continuing their unlawful conduct and requiring them to take affirmative steps to dissipate the effects of their prior conduct;

D. An award to Plaintiffs of the costs of this suit, including reasonable attorneys' fees as provided by law; and

E. Such other and further relief as the Court deems just and appropriate.

## XII. JURY DEMAND

Plaintiffs demand a trial by jury of all issues so triable.

Dated: October 14, 2013

Respectfully submitted,

/s/ *Christopher A. Seeger*

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